FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
Endocrinologic and Metabolic Drugs Advisory Committee
Hilton Hotel, Washington DC/Silver Spring, Maryland
8727 Colesville Road, Silver Spring, Maryland
May 19, 2011

AGENDA

The committee will discuss the findings of the Action to Control Cardiovascular Risk in Diabetes-Lipid (ACCORD Lipid) trial as they relate to the efficacy and safety of the approved new drug application (NDA) 22224, TRILIPIX (fenofibric acid) delayed-release capsules, manufactured by Abbott Laboratories.

8:00 a.m.– 8:05 a.m.	Call to Order and Introductions	**Allison B. Goldfine, M.D.** *Acting Chair* Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC)
8:05 a.m. – 8:15 a.m.	Conflict of Interest Statement	**Paul T. Tran, R.Ph.** Designated Federal Officer, EMDAC
8:15 a.m. – 8:30 a.m.	Introduction/Background	**Eric C. Colman, M.D.** Deputy Director Division of Metabolism and Endocrinology Products (DMEP) Office of Drug Evaluation (ODE) II Office of New Drugs (OND) Center for Drug Evaluation and Research (CDER) Food and Drug Administration (FDA)
	GUEST PRESENTATION	
8:30 a.m. – 9:15 a.m.	The ACCORD Lipid Trial: In Depth Examination of the Results	**Henry Ginsberg, M.D.** Director Irving Institute for Clinical and Translational Research Columbia University
9:15 a.m. – 9:30 a.m.	Clarification Questions for Guest Speaker	
9:30 a.m. – 9:45 a.m.	**BREAK**	
9:45 a.m. – 11:15 a.m.	Sponsor Presentation	**Abbott Laboratories**
	Overview	**James Stolzenbach, Ph.D.** Dyslipidemia Divisional Vice President Abbott Laboratories
	Data Presentation	**Maureen Kelly, M.D.** Dyslipidemia Project Director Abbott Laboratories
	Clinician Perspective	**Peter Jones, M.D.** Associate Professor Baylor College of Medicine

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	Closing Remarks	**James Stolzenbach, Ph.D.** Dyslipidemia Divisional Vice President Abbott Laboratories
11:15 a.m. – 11:30 a.m.	Clarifying Questions from the Committee to Sponsor	
11:30 a.m. – 12:30 p.m.	**LUNCH**	
12:30 p.m. – 1:40 p.m.	**FDA PRESENTATION**	
12:30 p.m. - 12:40 p.m.	Fibrate and Statin Concurrency Analyses	**Vicky Borders-Hemphill, Pharm.D.** CDR, USPHS Commissioned Corps Drug Utilization Analyst Division of Epidemiology II (DEPI) Office of Pharmacovigilance and Epidemiology Office of Surveillance and Epidemiology (OSE) CDER, FDA
12:40 p.m. – 1:10 p.m.	Hospitalized Rhabdomyolysis with Combined Statin/Fibrate Use - Observational Evidence Submitted by the Sponsor in the Context of the Trilipix Postmarketing Requirement	**Christian Hampp, B.S. Pharm., Ph.D.** Epidemiologist Division of Epidemiology I (DEPI) Office of Pharmacovigilance and Epidemiology OSE, CDER, FDA
1:10 p.m. – 1:40 p.m.	Statin-Fenofibrate Combination Therapy after the ACCORD-Lipid Trial	**Iffat Nasrin Chowdhury, M.D.** Clinical Reviewer Division of Metabolism and Endocrinology Products (DMEP) ODE II, OND, CDER, FDA
1:40 p.m. – 2:00 p.m.	Clarifying Questions from the Committee to FDA	
2:00 p.m. – 3:00 p.m.	Open Public Hearing Session	
3:00 p.m. – 3:15 p.m.	**BREAK**	
3:15 p.m. – 5:00 p.m.	Discussion/Questions to the Committee	
5:00 p.m.	**ADJOURNMENT**	